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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,068	09/29/2003	Ren-Yo Forng	CI-0024	4724

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EXAMINER

BRADRICK, THOMAS DALE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/672,068

Applicant(s)

FORNG ET AL.

Examiner

Thomas D. Bradrick

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-176 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-176 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 8-21, 55-118, 121-142, and 148-176, drawn to a method for sterilizing a preparation of urokinase comprising irradiating the preparation with radiation for a time effective to sterilize the preparation, classified in class 422, subclass 23.
- II. Claims 2 and 4-176, drawn to a method for sterilizing a preparation of urokinase comprising irradiating the preparation with radiation at an effective rate and for a time effective to sterilize the preparation, classified in class 422, subclass 23.
- III. Claims 3, 8-21, 55-118, 121-142, and 148-176, drawn to a method for sterilizing a preparation of urokinase comprising irradiating the preparation with radiation to a total dose effective to sterilize the preparation, classified in class 422, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

The processes are distinct from one another because they recite different and distinct steps.

The several inventions listed above are independent and distinct from one another as they require independent searches, particularly with regard to the literature

searches. Clearly, a reference that would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

This application contains claims directed to the following patentably distinct species: processes; solvent reduction methods; single stabilizers; mixtures of stabilizers; dipeptide stabilizers; sources of urokinase; and biological contaminants. The species are independent or distinct because they are drawn to different methods and compositions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 22, 36, 37, 39, 105-109 and 112 are generic.

If electing Group 2, please elect a single species from claim 2, namely adding to the preparation of urokinase at least one stabilizer, reducing the residual solvent content of the urokinase preparation, reducing the temperature of the urokinase preparation, reducing the oxygen content of the urokinase preparation, adjusting or maintaining the pH of the urokinase preparation or adding to the urokinase preparation at least one non-aqueous solvent; a single species from claim 22, namely lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying or vitrification; a single species from claim 36, namely ascorbic acid, glutathione, vitamin E, albumin, sucrose, glycylglycine, L-carnosine, cysteine, silymarin, diosmin, hydroquinonesulfonic acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, uric acid, methionine, histidine, N-acetyl cysteine, lipoic acid, sodium formaldehyde

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sulfoxylate, gallic acid, propyl gallate, ethanol, acetone, rutin, epicatechin, biacalein, purpurogallin, pyruvate or lactate; a single species from claim 37, namely mixtures of ethanol and acetone, mixtures of ascorbic acid and uric acid, mixtures of ascorbic acid and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, mixtures of ascorbic acid, uric acid and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, mixtures of ascorbic acid, uric acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid and albumin, mixtures of ascorbic acid, uric acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose, mixtures of ascorbic acid and glycylglycine, mixtures of ascorbic acid, glycylglycine and albumin, mixtures of ascorbic acid and L-carnosine, mixtures of ascorbic acid and cysteine, mixtures of ascorbic acid and N-acetyl cysteine, mixtures of ascorbic acid, uric acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid and silymarin, mixtures of ascorbic acid, uric acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid and diosmin, mixtures of ascorbic acid, uric acid and lipoic acid, mixtures of ascorbic acid, uric acid and hydroquinonesulfonic acid, mixtures of pyruvate and lactate, mixtures of pyruvate and ascorbate, mixtures of pyruvate and histidine, and mixtures of uric acid, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and a single species from claim 39, namely glycyl-glycine, carnosine or anserine.

For election of any of Groups I-III, please select a single species from claims 105-109, namely bovine, ovine, porcine, equine or caprine; and a single species from claim 112, namely viruses, bacteria, yeasts, molds, fungi, parasites or prions.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is 571-272-

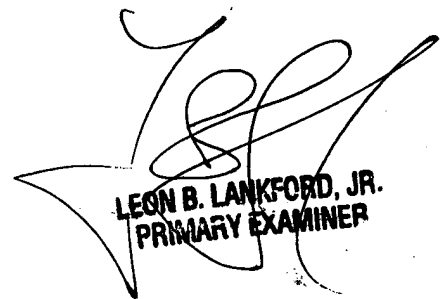
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8139. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached at 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Bradrick  
Patent Examiner  
Art Unit 1651



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER